

fibrillation (VT/VF), post-operative stroke (CVA), and post-operative myocardial infarction (MI).

**Methods:** We conducted a meta-analysis to assess the effect of peri-operative amiodarone on the incidence of morbidity and mortality. MEDLINE, CINAHL, Cochrane Central Register of Controlled Trials, and EMBASE databases were searched through 5/2003 with the terms *atrial fibrillation*, *amiodarone* and *surgery*. Inclusion criteria were randomized controlled double-blind study design and primary outcome designated as incidence of AF/AFL. AF/AFL, VT/VF, CVA, MI, and mortality data were pooled using the DerSimonian-Laird method with a random effects model. Trial heterogeneity was assessed via the Woolf Q statistic, and publication bias was assessed with Kendall's test on standardized effect vs. variance.

**Results:** Eight randomized controlled double blind placebo trials with a total of 1,527 patients were included in our analysis of the incidence of AF/AFL and mortality. Of these, six trials (1,184 patients) reported data on VT/VF, CVA, and MI. Heterogeneity and publication bias were not detected. Amiodarone significantly decreased the incidence of AF/AFL [odds ratio 0.539, 95% CI (0.428, 0.678),  $P<0.0001$ ], VT/VF [odds ratio 0.308, 95% CI (0.164, 0.579),  $P=0.0003$ ], and CVA [odds ratio 0.434, 95% CI (0.203, 0.929),  $P=0.0315$ ], when compared to placebo. Amiodarone did not significantly decrease the incidence of MI [odds ratio 0.821, 95% CI (0.265, 2.543),  $P=0.732$ ] and had no impact on mortality [odds ratio 1.043, 95% CI (0.460, 2.370),  $P=0.919$ ].

**Conclusion:** Amiodarone significantly reduced not only the incidence of AF/AFL, but also of VT/VF and CVA. This study has important clinical implications and illustrates the need for future prospective studies adequately powered to detect reductions in cardiovascular morbidity and mortality.

## POSTER SESSION

### 1172 Outcomes of Care

Tuesday, March 09, 2004, 3:00 p.m.-5:00 p.m.

Morial Convention Center, Hall G

Presentation Hour: 4:00 p.m.-5:00 p.m.

1172-67

#### Use of Administrative Databases May Lead to Incorrect Estimates of the Effects of Nonaspirin Nonsteroidal Anti-Inflammatory Drugs on Myocardial Infarction Risk

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**Background:** Studies using administrative, prescription databases have generally shown no effect of most nonselective non-aspirin nonsteroidal anti-inflammatory drugs (NANSAIDs) on cardiovascular risk. We analyzed data from a study that specifically addressed the biases inherent in using prescription databases to determine the effect of these potential biases.

**Methods:** In our case-control study of NANSAIDs and first MI, we determined the odds ratio for prescription (Rx) NANSAIDs versus non-users on MI risk as follows: (1) Replicating administrative database studies by: including over-the-counter (OTC) NANSAID users as "non-users," not excluding aspirin (ASA) users, and not adjusting for confounders typically unavailable in administrative databases (smoking, family history, body mass index, education, and physical activity). (2) Analysis #1 after removing OTC NANSAIDs from the "non-user" category. (3) Analysis #2, adding adjustment for the confounders listed above. (4) Analysis #3 plus excluding ASA users.

**Results:** OTC NANSAIDs accounted for 79% of all NANSAID use. ASA use was 28%. Replication of administrative database analyses led to a null result (table). As we removed each potential bias from our study, the OR moved further from 1.0 and indicated a significant benefit of NANSAIDs in the fully adjusted analysis (#4).

**Conclusion:** The inability to measure OTC NANSAIDs, exclude ASA users, and adjust for confounding may bias studies of prescription NANSAIDs and MI towards showing no effect.

Effects of Adjustment

Analysis (see text)	Odds Ratio (95% CI)
#1 Replicating Administrative Database Analysis	1.0 (0.7-1.3)
#2	0.9 (0.7-1.1)
#3	0.8 (0.6-1.0)
#4 - Fully adjusted	0.7 (0.5-0.9)

1172-68

#### Does Statin Therapy Reduce Contrast-Induced Nephropathy? An Analysis From a Large Regional Registry of Contemporary Percutaneous Interventions

Sanjaya Khanal, Nizar Attallah, Dean E. Smith, Eva Kline-Rogers, David Share, Michael J. O'Donnell, Mauro Moscucci, Henry Ford Hospital, Detroit, MI, University of Michigan, Ann Arbor, MI

**Background:** Intravascular administration of contrast media can have nephrotoxic effects particularly in patients with baseline renal insufficiency. Along with lowering serum cholesterol, statins have pleiotropic effects in the vasculature. It is unclear whether statin use has a protective effect against contrast-induced nephropathy (CN).

**Methods:** We evaluated 29,409 patients who had both baseline pre-procedure and peak

post-procedure serum creatinine measured at the time of their percutaneous coronary intervention (PCI). Baseline demographics and creatinine profile before and after the procedure were compared between patients who received pre-procedure statins and those who did not. CN was defined as increase in serum creatinine of  $>0.5$  mg/dl.

**Results:** Baseline clinical characteristics were similar between the 2 groups (table). When compared to patients who did not receive pre-procedure statins, patients on pre-procedure statins had a lower incidence of CN (4.9 vs. 6.8,  $p<0.0001$ ) and a trend towards reduction of nephropathy requiring dialysis (0.4 vs. 0.6,  $p=0.07$ ). After adjustments for comorbidities, pre-procedure statin use was associated with a significant reduction in CN (OR 0.81, 95% CI 0.72-0.92,  $p=0.0009$ ).

**Conclusions:** Pre-procedure statin use is associated with significant reduction in CN after contemporary PCI.

Statin use and CN

	Pre-statin	No Pre-statin	
Variable	N=11,017	N=18,392	p-value
Age (mean (SD)), yrs	63.6	63.6	0.78
Female (%)	33.9	35.4	0.008
Baseline Creatinine (mean mg/dl)	1.2	1.2	0.50
Percent with Baseline Creatinine 1.5+mg/dl	12.9	12.6	0.54
Percent with Baseline Creatinine 2.0+mg/dl	4.8	5.0	0.42
Peak Creatinine (mean mg/dl)	1.3	1.3	0.30
Peak Creatinine 1.5+mg/dl	14.5	15.8	0.003
Peak Creatinine 2.0+mg/dl	6.6	7.9	<0.0001
Renal Failure Requiring Dialysis	0.4	0.6	0.07
Contrast Nephropathy	4.9	6.8	<0.0001

1172-69

#### Early Use of Small Molecule Platelet Glycoprotein IIb/IIIa Inhibitors for All Acute Coronary Syndrome Patients Is Superior to Selective Use of Abciximab for Only Those Requiring Percutaneous Coronary Interventions

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**Background:** Selective use of medication may be important when several competing therapies are available. Tirofiban and eptifibatide are small molecule platelet GP IIb/IIIa inhibitors with benefit in acute coronary syndromes (ACS), but may not be as effective as abciximab during percutaneous coronary intervention (PCI). However, abciximab does not have proven efficacy in medical management of patients with ACS. No prior study has attempted to balance the competing benefits of a strategy of giving all ACS patients a small molecule versus a strategy of using abciximab only if a patient undergoes PCI.

**Methods:** A decision analysis examined two treatment options and estimated under what conditions one strategy was superior to another. The two strategies were (1) treat all ACS patients initially with a small molecule GP IIb/IIIa inhibitor or (2) selectively use abciximab only in ACS patients who ultimately undergo PCI. Sensitivity analyses were performed over a wide range of assumptions. The primary outcome was life expectancy, and cost effectiveness and bleeding were a secondary outcomes.

**Results:** The strategy of general use of a small molecule GP IIb/IIIa inhibitor on presentation with ACS resulted in an average life expectancy of 15.93 years, compared with 15.71 years for selective use (life years savings of 0.22 years). The superiority of the general use strategy persisted over all but extremes in sensitivity analyses. Preliminary cost analyses showed general use as economically attractive, with cost per life year of less than \$50,000 over a wide range of assumptions. There was a similar likelihood of major bleeding for patients with general use v. selective (6.5% v 6.1%).

**Conclusion:** General use of early GP IIb/IIIa inhibition in all patients presenting with ACS leads to better outcomes than selective use. A selective use strategy may be superior only if a patient is extremely likely to undergo PCI (over 90%) or there is virtually no reduction of events in medically managed patients receiving GP IIb/IIIa inhibition. When faced with these competing strategies, the clinician should consider the significant, cost effective benefits to general use of small molecule platelet GP IIb/IIIa inhibitors in ACS.

1172-70

#### Tolerability, Safety, and Efficacy of Beta-Blockade in Black Patients With Heart Failure in the Community Setting: Insights From a Large Prospective Beta-Blocker Registry

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**Background:** Conflicting data exist regarding the tolerability and efficacy of beta-blockade in Black patients with heart failure (HF). In randomized controlled trials bucindolol appeared to worsen clinical outcome in Blacks while carvedilol apparently improved outcome comparably to White patients.

**Methods:** The Coreg Heart Failure Registry (COHERE) prospectively evaluated the early and 1-yr tolerability, safety, and efficacy of carvedilol in 4,280 HF patients treated in the community setting.

**Results:** Prior to initiation of carvedilol, Black patients ( $n=523$ ) differed from White patients ( $n=3,433$ ) in demonstrating more severe symptoms (NYHA Class III/IV, 44.3% vs 35.3%,  $p<0.001$ ), more diabetes (37.1% vs 30.3%,  $p=0.002$ ), less history of ischemic